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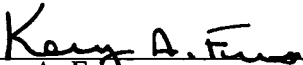
Philip S. Johnson, Esq.  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NEW JERSEY 08933-7003

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,826,868

Dear Mr. Johnson :

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,826,868 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:  
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to Mary C. Till by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

  
Kery A. Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Beverly Friedman

RE: ZUBRIN®  
FDA Docket No.: 2003E-410

**UNITED STATES PATENT AND TRADEMARK OFFICE**

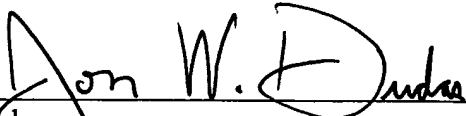
In re Ortho Pharmaceutical, Inc. :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 4,826,868 : INTERIM EXTENSION

Ortho Pharmaceutical, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,826,868, filed an application for interim patent term extension under 35 U.S.C. § 156 on March 24, 2006. The original term of the patent is due to expire on May 29, 2006. The patent claims the active ingredient, tepoxalin, in the animal drug product ZUBRIN®, which was approved by the Food and Drug Administration for commercial marketing or use on March 31, 2003. An interim extension of one year is requested under 35 USC § 156(e)(2).

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,826,868 is granted for a period of one year from the original expiration date of the patent.

5/17/06  
Date

  
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Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office